FACT

FOOD ANIMAL CONCERNS TRUST
411 W. FULLERTON PARKWAY, #1402W
POST OFFICE BOX 14599
CHICAGO, ILLINOIS 60614

FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00N-0504

April 19, 2000

To whom it may concern:

Enclosed please find The Comments of Food Animal Concerns Trust About the Egg Safety Action Plan.

Thank you for providing this opportunity for communication regarding this important food safety issue.

Sincerely,

Richard Wood
Executive Director

Meryl Camin Sosa
Manager, Food Safety Programs

00N-0504

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PHONE (773) 525-4952 FAX (773) 525-5226

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POST OFFICE BOX 14599
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The Comments of Food Animal Concerns Trust

About the Egg Safety Action Plan

April 19, 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

DOCKET NO. 98-045N3

UNITED STATES FOOD AND DRUG ADMINISTRATION

DOCKET NO. 00N-0504

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates for better farming practices to improve the safety of meat, milk, and eggs and to promote the humane husbandry of food animals. In 1984, FACT launched its NEST EGGS® program, a model egg farming system, in which our Pennsylvania farms have included controls for Salmonella enteritidis (SE) since 1991. We market eggs in major grocery store chains on the East Coast.

FACT calls on the Food Safety and Inspection Service of the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to use the Egg Safety Action Plan (the Plan) to develop a mandatory federal program with uniform standards designed to eliminate the threat of SE in shell eggs. This national program with uniform standards will address the food safety concerns of consumers and provide a level playing field for all producers.

PHONE (773) 525-4952 FAX (773) 525-5226

1. **Does the Egg Safety Action Plan comprehensively cover the problem of SE in eggs and measures for reducing this hazard? If not, what should the Plan include to be more complete**?

1. A Central Information Database: The Plan should include a requirement that results from farms operating under Strategy I should be forwarded to a central authority (FDA, Centers for Disease Prevention (CDC) or other) in a format that includes, as identifying information, only the state in which the farm is located but not any other identifying information. Collection of this information would be useful in determining the actual incidence of SE in shell eggs. The only other methods of surveillance rely on determining the incidence of SE in shell eggs by inference from information derived from SE outbreaks. This may not provide an accurate picture of the actual incidence of SE. Finally, this centralization of information would provide a measure of the success of the Egg Safety Action Plan (the Plan) by analyzing the results of the sampling protocol combined with data obtained from any tracebacks that have been conducted.

2. A single agency with responsibility for the safety of shell eggs. The continuation, by the Plan, of the division of responsibility for ensuring the safety of shell eggs between three departments of two agencies will carry on many of the same deficiencies existing in the current system.
First, confusion on the part of producers and consumers will continue. For example, the Plan merely states that "FDA" will develop standards for egg producers that the States and FDA will enforce. However, the Plan does not disclose which department or departments within FDA will perform these functions.

   Second, nothing within the Plan addresses the issue of conflicting mandates within the same agency. For example, part of the USDA's purpose is to both promote egg sales and to regulate portions of the egg industry. When the USDA permits producers to affix the "USDA Grade A" stamp on egg cartons, which mandate is being fulfilled? Consumers may believe that the stamp certifies they are purchasing a safe product. In fact, the stamp is a promotional tool signifying that the egg meets certain quality standards, not food safety criteria.[1] The USDA regulation regarding the stamp does not include any provision for the prevention of SE. In the final analysis the juxtaposition of these two purposes within one agency conceivably places the interests of the food industry over and against the food safety needs of consumers. Nothing in the Plan addresses this source of confusion to producers and consumers as well as the possible conflicting mandates.

   Third, the Plan fails to include any mechanisms for coordination between FDA, the Food Safety and Inspection Service (FSIS), and the USDA-

[1] Regulations Governing the Grading of Shell Eggs (7 CFR 56) and U.S. Standards, Grades, and Weight Classes for Shell Eggs (AMS 56).

Agricultural Marketing Service (AMS) on issues related to egg safety. While FACT continues to believe that a single egg agency would be the best organizational option for ensuring the safety of shell eggs, if coordination among the existing agencies is the option chosen, then some method of coordination among the agencies should be specified in order to avoid duplication of efforts, allow for clear roles and responsibilities, and to ensure efficient and effective enforcement of regulations regarding egg safety. For example, the Plan fails to state whether FSIS will continue to employ 120 inspectors for the purpose of inspecting egg product plants. In a single egg agency, the head of the agency would recognize that using 120 inspectors to inspect the safest area of the shell egg continuum is a tremendous waste of resources and would redeploy such funds and employees to other areas of the continuum, such as on farm, where they would be better utilized. Since FSIS will continue in its current role, and the Plan does not provide for a position with responsibility for oversight of the entire continuum, it may be assumed that this anomaly will continue. This example provides a clear illustration of the problem of having multiple agencies overseeing the issue of shell egg safety.

Fourth, FACT disagrees with the use of AMS as the agency for enforcement of performance standards for packers and egg products processors. AMS is an inappropriate choice. AMS' only role with regard to eggs, to date, has been to assist in the marketing of eggs by ensuring that eggs from those producers participating in the USDA Grading program, meet USDA's quality standards.[2] Of course, it should be noted that only one-third of egg producers participate in the voluntary AMS egg grading program.[3] Thus, AMS does not have the expertise to support an egg safety department

Fifth, the Plan leaves enforcement of on-farm regulations to the FDA and the States. This is not a viable option as it allows for variation among the States since states have different priorities and fiscal abilities. For example, some states may not place a high priority on egg safety and, therefore, will not allocate sufficient funds towards enforcement of egg safety regulations. This may lead, as it has with hog concentrated animal feeding operations (CAFOs), to egg producers making their siting decisions based on the strength of a state's egg safety enforcement program. This should not be permitted.

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[2]United States General Accounting Office Report to the Honorable Richard J. Durbin, U.S. Senate, FOOD SAFETY: U.S. Lacks a Consistent Farm-to-Table Approach to Egg safety, July, 1999. The GAO Report states that AMS has recently offered two programs that also address egg safety. The GAO Report states that one program is a voluntary HACCP-like sanitation program (which very few producers are using) and a voluntary fee-for –service program to conduct third-party monitoring for the UEP Five Star program. GAO Report at pp. 34-35. However, according to a Memorandum of Understanding between UEP and USDA-APHIS, executed August 3, 1999, the voluntary fee-for-service program to conduct third-party monitoring is actually offered by USDA-APHIS. UEP Conceptual Framework.

[3] United States General Accounting Office Report to the Honorable Richard J. Durbin, U.S. Senate, FOOD SAFETY: U.S. Lacks a Consistent Farm-to-Table Approach to Egg safety, July, 1999 at 11.

3. A prohibition on the practice of force molting. Researchers have demonstrated that where molting is induced, there is a decrease in the resistance of hens to SE and an increase in the incidence of SE shedding.[4] As a result, SE can readily be transmitted among hens (both molted and not molted). The combined effect of acutely susceptible hens exposed to SE results in increased transmission of SE.[5] In addition, every hen must eat every four hours.[6] Thus, after four hours of feed withdrawal the hens will begin to eat feces[7], which would include SE organisms if any of the hens have SE and are shedding. FACT recommends that the practice of induced molting should be discontinued as part of the program to eliminate SE in shell eggs.
The Salmonella Enteritidis Risk Assessment (SERA) found that molting is associated with an increased rate of SE positive eggs within SE positive flocks and, therefore, used molting as a factor in its assessment. On the other hand, the SERA at several points appeared to minimize the potential impact of molting as a factor in the incidence of SE.

First, the SERA estimates that 22% of flocks producing eggs on any given day are flocks that were previously molted.[8] While this may be true, this percentage fails to represent the full molting picture. In fact, according to the results of the National Animal Health Monitoring System (NAHMS) Layers '99 study, 82.6 percent of farm sites routinely molt their layers.[9] Further, according to the study, not only were almost all flocks in the western region molted, 32.1% of the last completed flocks were molted twice![10] Thus, it is clear the practice of force molting is widely used in the United States.

Second, the SERA states that SE positive flocks that are molted do not perpetually produce SE positive eggs more frequently than flocks that are not molted. Instead, according to the SERA, there appears to be a period immediately after molt when molted flocks are at higher risk of producing

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[4] Holt, PS and RE Porter, Jr., Effect of Induced Molting on the Course of Infection and Transmission of Salmonella enteritidis in White Leghorn Hens of Different Ages, Poultry Science 71: 1842-1848 (1992); Holt, PS, and RE Porter, Jr., Effect of Induced Molting on the Recurrence of a Previous Salmonella enteritidis Infection, Poultry Science 72:2069-2078 (1993); PS Holt Horizontal Transmission of Salmonella enteritidis in Molted and Unmolted Laying Chickens, Avian Diseases 39:239-249 (1994).

[5] Holt, PS, et al. Microbiological Analysis of the earliest Salmonella enteritidis Infection in Molted and Unmolted Hens. Avian Diseases 39:55-63 (1995); PS Holt, Predisposing Factors, International Symposium of Food-Borne Salmonella in Poultry, July 25-26, 1998.

[6] S. Russell, Effect of Poultry Processing on Populations of Bacteria on Fresh Broiler Chicken Carcasses, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998.

[7] Id.

[8] SERA at p. 40.

[9] National Animal Health Monitoring System (NAHMS) Layers '99, Part II: Reference of 1999 Table Egg Layer Management in the U.S., January 2000 at 17. In certain regions of the United States, the percentage of flocks molted was even higher: 97 percent of the flocks in the Southeast and 94.9 percentof the flocks in the West were force molted.

[10] Id.

more positive eggs.[11] On the other hand, the Schlosser study found that molted flocks not only produced SE positive eggs twice as frequently as non-molted flocks, but also molted flocks produced SE contaminated eggs for a period of up to 140 days post-molt.[12] Still, the SERA concluded that SE positive flocks will produce more positive eggs during the first 70 days post-molt. Their conclusion is intended to minimize the impact of the molting factor. Despite this attempt at minimization, it is clear that SE can persist in eggs from molted flocks.

Third, the SERA stated that infected hens typically produce SE positive eggs only during the first week of their four week infection.[13] Also, the SERA estimated that a positive hen in her first week of infection only produces SE positive eggs 8% of the time during that week. Thus, the SERA estimated an SE positive egg frequency of six SE positive eggs per 100,000 eggs produced in flocks detected through environmental testing or spent hen survey methods.[14] From this statistic, the SERA proceeds to make other conclusions. However, these statistics fail to recognize other factors which may increase the importance of molting as a factor in the spread of SE. First, as discussed above, once the SE organism is in the layer house, it can live for long periods in dust in the flock house and can even survive cleaning and disinfection.[15] Thus, even assuming the hens recover after four weeks, recurrence of infection, through retransmission via rodents and pests[16], is entirely possible due to the continued existence of the organism in the house. Second, unless there is environmental testing of the house and/or testing of the eggs, the producer cannot be certain whether the flock is SE free once the flock returns to production. For these reasons, if the practice of induced molting is to be permitted then mandatory post-molt environmental tests should be implemented.[17] This measure has already been incorporated into PEQAP.

Finally, despite the fact that a recent study found that antibiotics (such as enrofloxacin) combined with competitive exclusion culture may be an effective therapy against SE in molted hens, the researchers concluded that

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[11] SERA at p. 42.

[12] Schlosser, W., Henzler, D., Mason, J., Hurd, S., Trock, S., Sischo, W., Kradel, D., and Hogue, A., Salmonella enteritidis Pilot Project Progress Report. Washington DC (1995).

[13] SERA at p. 51.

[14] Id.

[15] Wray C. and R. Davies, Big Fleas Have Little Fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 (Salmonella can survive for long periods in dusts in poultry houses despite cleaning and disinfection).

[16] Id.

[17] The Pennsylvania Egg Quality Assurance Program requires that manure be tested in molted flocks at five to seven weeks following return to feed and that eggs must be tested as well.

"widespread administration of antibiotics to molted flocks cannot be recommended."[18] This is because salmonellae are

> "notoriously resistant to many antibiotics and are capable of rapidly developing resistance when exposed [and, therefore] antibiotic prophylaxis or treatment may actually increase the frequency and severity of Salmonella Enteritidis infection in hens. [ ] Furthermore, some antibiotics augment the chicken's susceptibility to salmonellae. [ ] Oral administration of antibiotics could also facilitate the proliferation of other resistant enterobacterial organisms and result in the transmission of antibiotic resistance between species residing in the intestinal tract."[19]

4. Indemnification: While this issue would not reduce the hazard of SE, the issue of indemnification is relevant and important to producers and should be included in any set of SE regulations as it will serve as an incentive for compliance. This issue is actually comprised of two components. First, FACT advocates that SE free chicks be provided to pullet houses. If a producer tests the chick papers upon delivery and finds that the chicks are contaminated, then the breeder should be required to provide a new batch of uncontaminated chicks. Currently, breeders do not maintain extra stocks of chicks for such emergencies. Instead, if such an occurrence arises, the producer must order new chicks and the flock houses must remain dormant, thereby creating a financial hardship for the producer. Thus, if the breeder fails to provide replacement chicks, then it should be required to financially indemnify the producer for any losses incurred as a result of the inability to commence the flock in a timely fashion.

   The second indemnification issue occurs when diversion of eggs is required when a layer house is found to be SE positive. On this issue, FACT agrees with the United Egg Producers' (UEP) proposal that indemnification should be provided to the producer at the "dollar value of difference between the shell egg market value and breaking stock egg value."[20]

5. Expiration Date: A federal rule should be enacted and implemented that specifies the components of the expiration date so that the expiration date has a specific meaning across the country. First, a determination should be made whether the date of lay or the date of processing will be used as the date that starts the clock running for purposes of determining the expiration date. Second, it must be determined whether the period should expire 30 or 45 days from the commencement date. By establishing a nationwide uniform

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[18] Seo, KH, PS Holt, RK Gast, and CL Hofacre, Combined Effect of Antibiotic and Competitive Exclusion Treatment on Salmonella Enteritidis Fecal Shedding in Molted Laying Hens, Research Note, Journal of Food Protection, Vol. 63, No. 4, 2000, pages 545-548.

[19] Id.

[20] UEP Conceptual Framework at p. 4.

expiration date, consumer confusion will be diminished and consumer confidence increased. Currently, because there are no federal rules specifying the requirements of the expiration date for shell eggs, consumers do not know what the expiration date on the egg carton means, nor how far beyond the expiration date eggs may be kept safely. Consumers will know how long eggs can be safely kept at home after the expiration date. By creating an expiration date with a nationwide uniform meaning, fact sheets can be distributed to consumers that indicate how long after the expiration date the eggs may be kept safely in a refrigerator, if at all.

2. **What are the costs and benefits of implementing each risk reduction component in the Action Plan**?
Based on the costs incurred by NEST EGGS® on its farms, the cost of the entire program, on a per flock basis, would be $3469.00. [Please see FACT's response to question 23 for an itemized breakdown]. The highest cost of the plan would be the SE environmental testing program. Also, this element is higher than in other quality assurance program because testing is conducted at various points during the layers' lives, rather than solely two to three weeks prior to depopulation. While this causes a large increase in the cost of the program, FACT believes this is justified for two reasons. First, by isolating SE in a timely fashion, responsive action can be taken if SE is found during the life of the flock. Second, by not allowing contaminated eggs to be marketed, more consumers will be protected.

3. **What training should be associated with respect to each component of the Action Plan**?
   - The FDA should train and certify laboratories conducting SE testing so that the issue of the testing competency of the laboratory is removed as a factor in evaluating a producer's compliance with the program.
   - The FDA should train producers and/or third parties who will be performing the on-farm environmental sampling program.

4. **Are the following appropriate and adequate components for a nationwide SE reduction program: Bio-security, SE-negative feed, chicks from SE-monitored breeders, flock health monitoring program, cleaning and disinfection of houses, rodent/pest control, monitored water supply**?
Yes with the following modifications and/or clarifications. First, a component prohibiting the practice of force molting should be added. [Please see discussion at page 4] Second, it is unclear what the phrase "flock health monitoring program" means. If it is synonymous with an SE environmental testing program, then the components listed are adequate for a nationwide SE reduction program, assuming that the testing program is adequate. What constitutes an adequate SE environmental testing program will be discussed under question 6. If the phrase "flock health monitoring program" does not refer to an SE environmental testing program, then the components listed under question 4 are insufficient as SE environmental testing is

essential for verifying the effectiveness of an SE reduction program. This will be discussed further under question 6.

5. **How effective do you think each component would be? Which component(s) do you think will provide the most risk reduction**?
No single component listed above can act as a silver bullet in protecting the public from SE in shell eggs. The SE reduction program must include all the on-farm elements to provide adequate protection to consumers.

- First, the requirement that only SE free chicks be placed in the pullet house is crucial because even if a "small percentage of Salmonella-positive eggs enter the hatching cabinet, the spread of Salmonella from these eggs can be extensive."[21] Chicks are extremely susceptible to Salmonella contamination because they do not develop immune systems until they are 10 days old. In addition, hatchery contamination can limit the effectiveness of competitive exclusion.[22] Further, a recent study found that Salmonella could be found inside the beak of chicks which were still in the egg but ready to hatch.[23] Here also competitive exclusion would be ineffective since colonization had already occurred. Since it is not possible to totally prevent SE contamination in the chicks, testing of chicks is a necessary component of any SE elimination program.
- Second, there now appears to be a consensus among industry and consumer groups concerning the importance of rodent control.[24] A study by the Agricultural Research Service of the USDA found, after two years of sampling more than 1000 mice from commercial poultry houses, that SE was in the spleen of one out of five of the mice.[25] It is believed that contaminated mice can survive usual cleaning and disinfectant procedures and could cause some clean houses to become SE positive even though no chickens are introduced. At night, mice eat from the feed trough and deposit an average of 100 pellets per mouse in the feed trough in a 24 hour period. Those pellets are the first items consumed by the chickens when the lights are turned on.[26] Research has found that mice may excrete Salmonella intermittently for at least 18 weeks.[27] Therefore, mice can recontaminate hens after an SE infection has occurred during a molt. Also, they can move out of the

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[21] Bailey, J.S., Cason JA, and NA Cox, Effect of Salmonella in Young Chicks on Competitive Exclusion Treatment. 1998 Poultry Science 77:394-399.
[22] Id.
[23] Nelson Cox, Incidence and Impact of Salmonellae in Broiler Hatcheries, International Symposium on Foodborne Salmonella in Poultry, July 25-26, 1998.
[24] See, e.g., United Egg Producers' "5-STAR" Top Quality Assurance Program (A HACCP type food safety program with validation.).
[25] New Clues on Salmonella, USDA-Agricultural Research Service News Service, Fsnet 4/28/97
[26] Charles Beard & Richard Gast, Where are we with SE, Egg Industry, July/August 1992; Clifford Wray, Big Fleas Have Little fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 ("Chickens find mice feces very palatable.").
[27] Clifford Wray, Big Fleas Have Little fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998

buildings during cleaning and disinfection and return thereafter to contaminate the house.[28] Thus, rodent control is a crucial part of any SE elimination program and most of the quality assurance plans (QAPs) have included this as a step in their programs.

- Third, the implementation and maintenance of an on-farm biosecurity program has been included as a step in all QAPs and must be included in the mandatory national program. The goal is to make the facility rodent and pest proof. An adequate biosecurity program is comprised a series of rules "for the location and design of farms, movement of personnel and equipment; manufacturing and distribution of feed; rodent and pest control; cleaning and disinfection procedures; disease surveillance and risk assessment."[29] All employees must be trained concerning the program and must participate in the program. The biosecurity program is ongoing and must be constantly monitored and maintained.

- Fourth, researchers have found Salmonella in feed[30] both in animal and plant protein. Thus, feed is an additional source of transmission of the infection. In order to eliminate SE, producers must include a program for achieving effective control of Salmonella contamination of poultry feed.[31] One effective method of reducing Salmonella contamination in poultry feed is pelletizing feed through a heat process.[32] NEST EGGS® has found this method to be very effective. Other methods include a combination of heat and propionic acid[33] and yeast added to poultry feed.[34] Finally, in order to ensure that feed is salmonella free, it must be regularly tested.
- Fifth, cleaning and disinfection of layer houses is a useful management tool for controlling SE on farm. FACT's NEST EGGS® program includes this step in its SE protocol. As well, UEP has included this step as a required element of its 5-Star program.[35] However, cleaning and disinfection of houses must be coupled

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[28] Id.

[29] Rosales, AG, and Eric L. Jensen, Biosecurity and Disinfection for Salmonella Control, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998.

[30] McChesney, DG, Kaplan, G., and Patsy Gardner, Special Report: FDA survey determines salmonella contamination, FEEDSTUFFS, 2/13/95 at 20-23; H. Riemann, Bacteria in Feed, In: Proceedings of a Symposium on Feed Quality Assurance-A Systemwide Approach. September 18-19, 1990.

[31] SG McIlory, Control of Salmonella Contamination of Poultry Feeds, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998; Feed contamination an important factor in salmonella control, Poultry Times, 4/6/98 at p. 11.

[32] [32] McCapes, R.H., H.E. Ekperigin, W.J. Cameron, W.L. Ritchie, J. Slagter, V. Stangeland, and K.V. Nagaraja, Effect of a New Pelleting Process on the Level of Contamination of Poultry Mash by Escherichia coli and Salmonella, Avian Diseases 33:103-111, 1989.

[33] Matlho, G., Himathongkham, S., Riemann H., and Philip Kass, Destruction of Salmonella enteritidis in Poultry Feed by Combination of Heat and Propionic Acid, Avian diseases 41: 58-61, 1997.

[34] The Report of the 100th Annual Meeting of the United States Animal Health Association, Presentation by Dr. Stan Bailey in the Report of the Committee on feed Safety, October 12-18, 1996, at p. 169.

[35] However, it should be noted that the "Five-Star" program does not require testing, after cleaning and disinfection in flock houses where SE has been found prior to depopulation. Thus, the "Five-

with SE environmental testing where SE has been found in a house. Research has found that a single cycle of cleaning and disinfection may not be sufficient to purge the pathogen from the house. Thus, where SE has been found in a house, cleaning and disinfection must be followed by an environmental test to verify the removal of the pathogen from the house.

An SE environmental testing program would probably be the most critical element of an SE reduction program. Absent testing, there is no effective method for determining whether an SE reduction program is working until there is a consumer foodborne illness outbreak which is traced back to a particular farm. FACT does not advocate this method of verification of the SE reduction program.

6. **Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? If so, how often and when should testing be performed to ensure that the plan is working and that the consumer is protected from consuming SE-contaminated eggs?**

   Yes, environmental testing is an appropriate verification step to ensure that the risk reduction plan is working. The necessity of incorporating testing into any QAP has been recognized by a variety of groups and individuals.[36] Absent such testing, how does a producer know whether the layers are infected since infected layers are generally asymptomatic?[37]

   The UEP have, to some degree, recognized the importance of environmental testing by including environmental testing of the facility as a validation that the 5-Star Program is working.[38] Unfortunately, the testing in the UEP 5-Star Program is recommended to occur two to three weeks prior to depopulation. By this time, thousands of contaminated eggs could already have been produced and marketed.

Star" program assumes that the cleaning and disinfection will eliminate SE in a positive house and this may not be the case. Instead, the plan recommends a "third party walk through of facility, after cleaning and disinfecting (C&D) for visual inspection." While houses may visually appear to be clean, SE cannot be seen with the naked eye and SE can still exist even in houses that look clean.

[36] Dr. John Mason, Food Safety Consultant, has said that absent some type of testing for SE (at least of the environment), there cannot be any objective indication that QAP measures are effective. Food Safety Digest, May/June 1997 at page 5 (citing a presentation made by Dr. Mason at the Conference on Animal Production Food Safety held in conjunction with the Livestock Conservation Institute's 1997 annual meeting.) Petition for Regulatory Action to Require That (1) Warning Labels About the Risks of Salmonella enteritidis (SE) Be Placed on shell egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms, Submitted by the Center for Science in the Public Interest to the U.S. Department of Health and Human Services, Food and Drug Administration, 5/14/97, at p. 12, Richard D., and Gary D. Butcher, Special Report: Salmonella: Controlling it in the broiler, egg industries, FEEDSTUFFS, 10/11/93, Vol. 65, Number 42, at pp. 22-34, 45; Recommendations contained in the Salmonella Enteritidis Review Team Report prepared by Review Team 1/18/97 at pp. 10, 12.

[37] "Salmonella enteritidis silently infects the ovaries of healthy appearing hens and contaminates the eggs before the shells are formed." Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control Salmonella enteritidis Infection Web page, June 28, 1996; International Increase in Salmonella enteritidis, A New Pandemic, Epidemiologic Infection, 3/26/90 at p. 25.

[38] UEP "5-Star" Total Quality Assurance Program.

The SERA, released by the Food Safety and Inspection Service (FSIS), also demonstrates the need for testing, especially on large farms. The SERA found that by flock size strata, the largest stratum, flock sizes of 100,000 per flock, contributed almost two-thirds of SE positive eggs.[39] At a time when large egg production operations are becoming the norm, this SERA data in and of itself should be sufficient justification for required testing on all egg farms.

In terms of the test itself, FACT supports environmental testing over testing batches of eggs. Environmental tests provide a more accurate picture of whether or not the flock is contaminated. Infected hens do not produce contaminated eggs all of the time. Furthermore, not all hens in a flock house are infected by SE at the same time. Therefore, testing batches of eggs will not provide sufficient evidence to determine whether the flock house is contaminated by SE. On the other hand, since infected hens will shed SE, environmental samples provide greater certainty as to whether SE is present in the hens.

FACT recommends that the following testing protocol be implemented as it is based on the NEST EGGS® protocol which has been successful on its farms.

Pullets

- Test empty house 4 weeks before delivery. If positive, retest. If positives continue, the pullet house is not used.
- Test chick boxes. If SE is found, depopulate the chicks, disinfect house, test again, and replace the chicks.
- Test chicks at 5 to 15 days. If positive, test again in 7 weeks.
- Test at 10 to 15 weeks. If positive, pullets are not used.

Layers

- Clean and disinfect house. Test house before delivery. If positive, repeat test and divert eggs.
- Test at 29 to 31 weeks. If positive, divert eggs and test again in 4 weeks.
- Test at 44 to 46 weeks. If positive, divert eggs and test again in 4 weeks.

FACT does not force molt its flocks. However, in establishing an SE on-farm testing protocol for farms that do force molt their flocks, the protocol should include additional tests from each of the molted flocks at five to seven weeks following return to feed would be required.

As indicated above, NEST EGGS® cleans and disinfects each house after depopulation and then tests each house for SE. This test is critical because research has found that cleaning and disinfecting is not always sufficient to remove SE from a house. Recently, in an empty NEST EGGS® layer house that was being prepared for a new flock, the house tested positive after it had been cleaned and disinfected. Tests

[39] Salmonella Enteritidis Risk Assessment Report, July 1998 at p.63.

for Salmonella, performed on the flock a few weeks prior to depopulation, had been negative. Many participants at the March 30, 2000 meeting about the Plan supported the idea that a plan that included environmental SE tests two to three weeks prior to depopulation should be sufficient. However, this example illustrates the need for a more thorough environmental testing program. Even if a house has been cleaned and disinfected, tests must still be performed to ensure that an empty house is SE negative prior to placement of pullets in the layer house.[40]

Also, it was suggested, at the March 30, 2000 meeting, that the SE environmental testing program should include only a baseline test of all flocks. This test would be taken at two to three weeks prior to depopulation. A more extensive testing program would be required for those houses that tested positive. Dr. Robert Eckroade said that, in Pennsylvania, approximately fifteen percent of flocks are SE positive. However, since many of the flocks that would be in the new federal program have not been in any QAPs, it may be anticipated that, at least at the beginning of the program, the number of positive flocks would be closer to forty percent, representing the number of SE positive flocks in the SE pilot project at the beginning of the program in Pennsylvania.[41]

7. **In the event that an environmental sample for SE is positive, what, if any, additional steps should a producer be required to take with the positive flock/house and with the next flock that will be placed in that house?**

When SE is found in a flock house, eggs should be diverted to the breaker plant. Other additional steps that may need to be taken depend on when during the laying cycle the SE is found. Please see FACT's response to question 6.

8. **Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs?**

Research has found that killed vaccines can play a significant role in reducing fecal shedding of salmonella from infected birds. The vaccine will also decrease lateral spread of salmonella to susceptible birds.[42] However, vaccination alone is insufficient; rather, it must be used to supplement all other preventive and control measures.[43] Further, it should be noted that research is currently being conducted on live vaccines which may prove to be more effective than killed vaccines. Such research should be encouraged.

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[40] At the March 30, 2000, meeting concerning the Plan, Dr. Richard Dutton (sp?), of Michael Foods, stated that it can take up to three rounds of cleaning and disinfected for a flock house for test results to show the house to be SE negative.

[41] Salmonella Enteritidis Review team Report, January 18, 1997, at p. 9.

[42] KV Nagaraja and A Beck, Vaccination against Salmonella Infection: Killed and Subunit Vaccines, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 at 198.

[43] Id.

9. **In the event eggs from an SE-positive layer flock are diverted from the table egg market, what measures should be implemented to ensure those eggs are pasteurized?**
FACT is not aware of the proper steps necessary to ensure pasteurization of egg products. However, from an on-farm perspective, records must be created and maintained on farm to demonstrate compliance, by the farm, with diversion requirements. By maintaining such records for the period of one year, the farm can prove, in the event of an outbreak, that it properly shipped the contaminated eggs to a breaker plant. By doing this, the farm ensures that it will not be liable, in the event of an outbreak, and that the breaker will be responsible for any deficiencies in its pasteurization process. However, it should be recognized that pasteurization is not a substitute for a strong on-farm SE risk reduction program.

10. **In the event eggs from an SE-positive flock are diverted to the production of liquid, frozen, or dried egg products, should the eggs be handled or processed differently? Indicate the cost associated with the described process.**
No response

11. **Do customer specifications exist that prohibit the processing of SE-positive eggs for egg products? Considering your production volume and available market for egg products, will this influence the price for SE-positive eggs?**
No response

12. **What is an estimated cost to implement the proposed components of a HACCP-based system, including adequate good manufacturing practices to minimize the growth of SE and prevent cross contamination, for each of the following processing operations (include only the new costs incurred such as record keeping, company verification on a continuing basis, and revised processing procedures for conformance):**

a. **Packer of shell eggs for the consumer?**

b. **In-shell pasteurization of eggs?**

c. **HACCP in egg products establishments?**

No response.

13. **For the development of a performance standard(s) for the thermal processing of liquid eggs and other egg products, we are requesting information regarding the enumeration of SE in liquid eggs prior to pasteurization.**
No response.

14. **What is the cost of maintaining refrigerated storage (maximum temperature 60 F) for eggs received that are destined for grading and packaging or in-shell pasteurization, when time to processing will exceed 24 hours from time of lay?**

No response.

15. **Are there any methods by which a packer/processor can determine how old eggs are when they are received?**
No response.

16. **When packing shell eggs for the consumer, will the use of only new primary packing materials increase your marketing costs? If so, what is the estimated cost? Is there a way to clean plastic containers to prevent cross contamination so they can be re-used?**
NEST EGGS® currently uses only new primary packing materials except when eggs are going to be shipped to the breaker plant. Thus, this additional expense has always been incorporated into the NEST EGGS® SE prevention program.

17. **Are the proposed components of the national standards for packing and processing of shell eggs and egg products appropriate and adequate to reduce the risk associated with SE?**
First, the time and temperature regulations issued by FDA and FSIS should be reviewed. The FSIS regulation requires that eggs be stored at an ambient temperature of 45 degrees Fahrenheit, not an internal temperature of 45 degrees Fahrenheit. According to FSIS, in the United States General Accounting Office Report, Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO Egg Safety Report),

> "maintaining the internal temperature of eggs at 45 degrees or below throughout processing and distribution would result in a greater reduction in illnesses from SE than would result from an air temperature requirement. [¶] In contaminated eggs, SE is unlikely to grow at temperatures under 45 degrees. However, when eggs are processed and packed, according to USDA, they are often in the 70-to 80-degree temperature range. Because of the way eggs are packed, even if they are immediately put into a cooler, research has shown that it may take from 3 to 6 days before the egg's internal temperature is reduced to the air temperature. During this time, SE bacteria may replicate, and the more bacteria an egg contains, the more dangerous it will be if eaten raw or undercooked. [SERA] estimated, on average, an 8-percent reduction in human illness when eggs are maintained at an air temperature of 45 degrees. In contrast, the study estimated, on average, a 12-percent reduction in illness if eggs are cooled to an internal temperature of 45 degrees immediately after being laid."[44]

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[44] United States General Accounting Office Report to the Honorable Richard J. Durbin, U.S. Senate, FOOD SAFETY: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety, July 1999 at 10-11. The GAO Egg Safety Report discusses new technologies that show promise in achieving more rapid cooling at a relatively low cost.

> "Researchers at North Carolina State University have experimented with cryogenic gas to rapidly cool eggs. Their research found that during commercial processing, eggs could be cooled to 38 degrees within 12 minutes using cryogenic gases and that this approach would reduce the likelihood of Salmonella growth in or on eggs. One company has developed a prototype cooling

Thus, even FSIS does not agree that the temperature included in the regulations is sufficient to prevent SE and that a better option is available. Thus, the regulations, drafted in pursuance of the Plan, should revise the regulations to require an internal temperature of 45 degrees at all times once eggs have been processed.

Second, the only reference in the Plan to repackaging appears to include repackaging as a component. While USDA-AMS' temporarily prohibited the practice of repackaging and redating eggs, that prohibition would apply only to the one-third of the nation's eggs graded and packed under the AMS voluntary grading program. Further, FDA has not taken any measures to address this issue.

> "Two key risk factors can affect the growth of SE in eggs-age and temperature. Experts agree that an egg's natural defenses to SE can break down as an egg ages or is exposed to high or fluctuating temperatures. [¶]. . . . Eggs that are repackaged must be transported to the processing plant and therefore may be subject to temperature fluctuations as well as additional heating during rewashing. Because of these risk factors, concerns have surfaced about the practice of repackaging and redating shell eggs that are about to reach their expiration dates. Therefore, ensuring that eggs are fresh and are maintained under a consistent, appropriate temperature from packing to the table are critical SE reduction measures."[45]

Since repackaging presents another opportunity to allow SE contamination, this practice must be prohibited in all shell eggs-not only those eggs graded by AMS. This is a food safety issue-not only a quality issue and must be addressed accordingly.

18. **Do the provisions in the 1999 Food Code which apply to shell eggs adequately protect at-risk consumers in retail establishments? If not, what other provisions are necessary for their protection? (Note: The 1999 Food Code is available on the Internet under ``Federal/State Food Programs'' at www.cfsan.fda.gov.)** The Food Code is not an adequate solution for providing protection to at-risk consumers in retail establishments. The Food Code is only operable in states that have adopted its provisions. States are free to adopt any or all of the provisions of the Food Code. The GAO, in preparing the GAO Egg Safety Report, found that 24 of the 50 states did not require food service operators to serve highly susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs, such as Caesar salad dressing.[46] Further, the Food Code is not a federal regulation and only has the force of law when it has been adopted by a state or local

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method using cryogenic gases that will soon be tested in production. According to the company's estimates, this process will add about 3 cents or less to the cost of a dozen eggs. In addition, other research is being conducted on the use of forced cold air to cool eggs faster, . ." Id.

[45] Id. at 13.

[46] Id. at 12.

governmental entity and when sufficient penalties are imposed under the adopted provisions and the state adequately enforces such provisions. Thus, the reliance, by the FDA, on the Food Code as a method for protecting the safety of food is completely inadequate. Regulations should be included, as part of the Egg Safety Action Plan, that provide adequate protection for at-risk consumers in retail establishments rather than relying on the hit or miss approach offered by the Food Code. It cannot be emphasized enough that the Plan is an opportunity to provide a comprehensive regulatory approach to the issue of egg safety, providing regulations that truly govern all aspects of the farm-to-table continuum.

19. **Rewashing of shell eggs is a wide-spread industry practice. Are there data or research to support it? If it is disallowed, what economic effect will it have on the shell egg industry?**

No response.

20. **What research on SE in eggs is already underway and what additional research is needed to assist producers, packer/processors, and retailers in proper practices?**

- Research to develop an effective live vaccine for SE.
- Research that compares SE contamination rates between deep litter floor systems and cage systems.
- Research on the issue of which breeds of layers are more susceptible to SE (so that strains that are less susceptible to SE are used.)
- Research that determines the relationship, if any, between hen density in cages and the shedding of SE.
- Research to determine other stress factors that may increase the susceptibility of layers to SE.
- Research to understand the ecology of SE and the sources of SE in the environment.
- Research to improve testing methodologies for SE on the farm and in the egg, including the identification of virulence factors.
- Development of rapid tests for the detection of SE.

21. **To what extent are you already engaging in the following practices:**

a. Use of chicks from National Poultry Improvement Plan (NPIP) SE-monitored breeders?

NEST EGGS® uses only chicks from NPIP SE monitored breeders.

b. Rodent/pest control?

All NEST EGGS® farms contract with independent rodent control services to perform this function.

c. Bio-security?
NEST EGGS® farms have footbaths. Also, NEST EGGS® has a producer education plan to educate farmers on the use of bio-security measures on the farm.

d. Cleaning and disinfecting?
NEST EGGS® requires that each flock house must be cleaned and disinfected after each flock. Most of the farms use an independent company to perform this function.

e. Use of monitored water supply?
NEST EGGS® tests the water supply of each farm, for coliform bacteria and nitrates, once every six months.

f. Use of SE-controlled feed?
NEST EGGS® uses feed that has been pelletized. Also, feed samples are tested for Salmonella on a regular basis.

22. **Testing for verification on the on-farm plan. We are interested in your answers to the following questions for both environmental testing and egg testing:**

a. To what extent are you currently testing?
The testing protocol for SE in NEST EGGS® farms is as follows:

Pullets		
	Empty:	SE test 4 weeks before delivery
		If SE is found, test again
		If SE is still found, house is not used.
	Delivery:	Chick box SE test
		If SE, order replacement chicks
		House is disinfected, then, tested for SE again.
	5 to 15 days:	If SE, test again in 7 weeks
	10-15 weeks:	If SE is found, pullets are not used.
		Try to locate SE free replacements
	Empty:	Clean and disinfect
Layers		
		Empty 4 weeks before delivery
		Clean and disinfect house
		If SE is found, disinfect house and test again
		If SE is found again, use an alternate house OR divert eggs and test again at 22 weeks
		If SE is found, divert eggs and test at 29 weeks
		If SE is found, depopulate the house and buy tested pullets
	29-31 weeks	If SE is found, divert eggs
		Increase biosecurity
		Schedule extra SE test in 4 weeks

	If SE is found, depopulate and buy tested pullets
44-46 weeks:	If SE is found, divert eggs, and test again in 4 weeks
	If SE is still found, depopulate the house
Empty:	See above.

b. What is the sampling plan for the tests you conduct?

For chick papers, two samples are taken.

In pullet houses, six drag swabs are taken per house. The areas sampled are distributed throughout the house.

In layer houses, 18 samples are taken per house. Samples are taken from the slats, litter, and nests. Also, in the layer houses, one sample is taken from the egg room and one sample is taken from the cooler.

c. What tests do you use? Do you test for the presence of Salmonella, SE, SE stercotypes [serotypes], etc.?

Initially, NEST EGGS® farms test for the presence of Salmonella group serotypes. If Group D Salmonella is found in a house, then the sample is further serotyped to determine whether the Salmonella is SE.

d. How much do these tests cost (include separately both lab costs and on-farm labor costs)?

The testing of the chick papers and the pullets are not performed on the NEST EGGS® farms and the cost is included in the overall price of the pullets. For each set of 16 samples taken from a laying house, the on farm labor cost is $125.00. NEST EGGS® uses an independent poultry service to perform the sampling. Testing at the laboratory costs $16.50 per sample to test for Salmonella group serotypes. Further serotyping is an additional charge. Thus, for a normal test of a layer house, NEST EGGS® pays:

$125.00 (sampling charge) x $297.00 (16 x $16.50) = $422.00.

Thus, under the NEST EGGS® sampling protocol, the SE environmental testing program costs are $2500.00 which includes the on farm and laboratory work, but does not include office record keeping costs.

23. **How much would it cost you to implement each of the proposed components of the risk reduction plan? (Note: The costs you estimate should be the new costs you will bear in excess of what you are already spending on risk reduction.)**
    - Assuming a testing protocol similar to that already used by NEST EGGS®, the cost of the SE environmental testing would be $2500.00 per flock.
    - Assuming a flock size of approximately 5000 hens, the current cost of vaccination of a NEST EGGS® flock (single dose only) is $675.00.
    - The cost of cleaning and disinfecting a flock house is paid by the individual farmer and not NEST EGGS®. However, for purposes of this discussion the cost will be included in these calculations. The cost of cleaning out and disinfecting a house is $250 per flock.

- Water monitoring tests cost $36.00 per flock.
- Pelletizing feed costs approximately $8.00 per ton of feed. This increases cost of feed by five percent.

24. **What are the current market prices or costs you pay or get for the following:**

a. Chicks from NPIP SE-monitored breeders versus chicks from noncertified sources?

NEST EGGS® never purchases chicks from noncertified sources, so we do not have any comparative information. NEST EGGS® pays 56 cents per chick for chicks from NPIP SE-monitored breeders.

b. Grade A/B eggs versus breaker eggs?

NEST EGGS® receives 15 cents per dozen eggs for eggs sent to the breakers. For eggs marketed as NEST EGGS®, the Grade A price is based on the price for a niche market product.

c. Dry cleaning versus dry, wet disinfecting poultry houses?

NEST EGGS® farms do not use the dry cleaning process for its poultry houses. The cost for wet cleaning and disinfecting a layer house is $250.00.

d. SE-controlled feed versus noncontrolled feed?

NEST EGGS® does not use noncontrolled feed so that cost is unknown. As discussed earlier, NEST EGGS® uses pelletized feed which costs $8.00 per ton extra. In addition, the laboratory cost for testing a feed sample is $16.50.

25. **Can you get replacement chicks/pullets at a time different from your usual lay cycle? If so, what price premium, if any, would you have to pay to get these birds?**

Obtaining replacements chicks, at a time other that the usual cycle, is very difficult. Breeder farms want layer farms to place orders for chicks a year in advance. NEST EGGS® has never obtained replacement chicks so it has not had to address this issue as yet.

26. **Do you currently vaccinate your layers for SE? At what time(s)? What does it cost?**

NEST EGGS® commenced its vaccination program for all flocks hatched in the year 2000. Flocks are vaccinated at 10 to 12 weeks. The cost for the vaccine is 3.5 cents per dose. The labor charge for administration of the vaccine is ten cents per hen. Some additional cost is anticipated due to mortality normally associated with handling. Due to high labor costs, only one dose of the vaccine per hen is being administered at this time.

27. **Before processing or shipping for processing, are your eggs stored on the farm in an environment that is not temperature controlled? For how long? If so, what temperatures are the eggs stored at and how long do they stay in storage?**

Eggs are collected on NEST EGGS® farms twice a day. During the period between lay and collection, the eggs are not refrigerated. After the eggs are collected, they are stored in a temperature controlled cooler until they are processed.

28. **When you ship your eggs from the farm to the processor/ packer, do you reuse packing materials? What steps are taken to minimize any bio-security hazards that may arise from such a practice? How much would it cost to sanitize or use new packing materials for each egg shipment?**

Packing materials are reused only when the farm knows that the eggs are destined for the breaker plant. Otherwise, NEST EGGS® are shipped in carts. It is possible that the carts may be a source of SE and investigation into this issue is ongoing.

29. **To help us understand the viewpoint from which you are making your comments, it would be helpful for us to have some information about the structure of your firm. This will help us to determine whether your comment represents an additional perspective that we should consider. Answers to the following questions would be useful:**

a. In what State(s) do you currently operate?
Pennsylvania

b. How many layer houses do you have?
Thirteen

c. What style of house(s) is typical for your operation?
NEST EGGS® uses floor birds. The flock houses have litter, slatted areas and nest boxes. There are no cages on NEST EGGS® farms. The house stocking density is one hen for every two square feet.

d. What is the average number of layers in each house?
The average number of hens is 5000 per layer house.

e. Is yours an in-line or an off-line operation?
Off-line.

f. Do you currently molt your layers? If molting is used, when is it used?
No. Molting is not permitted on NEST EGGS® farms.

Conclusion:

For over ten years, the egg industry has hoped that the problem of SE in shell eggs would just go away. It is clear that the problem of SE has not been eliminated either by ignoring it or by establishing voluntary QAPs. In fact, the organism has mutated into an even more virulent form and has persisted as a consumer health problem. It is essential

that the FDA and USDA use the Plan as an opportunity to establish a mandatory federal program with uniform standards designed to eliminate the threat of SE in shell eggs. Such a program will provide assurances to the consumer and a level playing field for producers.

The cornerstone of the mandatory national program must be the inclusion of mandatory environmental testing for SE. Only through testing can a producer verify that the other elements of its SE elimination program are working. One-time testing two to three weeks prior to depopulation cannot serve this purpose. Testing must be conducted at specified intervals throughout the life of the flock including upon placement in the pullet house, placement in the layer house, post-molt and after depopulation of the flock house. Testing is also necessary to ensure the provision of SE free feed to flocks. Most egg producers agree that rodent and pest control programs and complete biosecurity programs are integral parts to the elimination of the organism from the farm. Finally, the national mandatory program must include a requirement that eggs be diverted to pasteurization where SE has been found in the flock house.

Another critical element to a successful SE risk reduction program would be the creation of a single federal egg agency. The Plan continues the current organizational structure where issues related to shell eggs have been addressed by several offices of the FDA and the USDA. This has not worked in the past and there is no reason to believe that it will work in the future. The same fundamental problems will continue to exist. Without a single individual responsible for oversight of the entire egg program, anomalies, such as FSIS having 120 inspectors for inspecting egg product plants while FDA has only a single inspector for on farm inspections, will continue to exist. The lack of centralization and coordination has made it difficult for producers to understand their regulatory responsibilities and to know who to contact in the event of questions or problems. Further, a single egg agency would make more sense from a budgetary standpoint since the head of the egg agency would make certain that all parts of the program were adequately funded. Also, by housing all aspects of the egg continuum within a single agency, expertise would be centralized and coordinated, and duplication, in both job duties as well all research, could be avoided.

While these steps are focused primarily on farm controls, FACT believes that if the on-farm component of the SE threat is controlled, a significant step towards the elimination of the threat of SE will have been accomplished. Thank you.

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